IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA, *ex rel.* [UNDER SEAL],	§	SA04CA0817 RF
Plaintiff	§	**CIVIL ACTION NO.**
	§	
vs.	§	**UNDER SEAL**
	§	
[UNDER SEAL],	§	
Defendant	§	

PLAINTIFF'S COMPLAINT UNDER 31 U.S.C. § 3730

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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA, *ex rel.* CAROL OREN,	§	
Plaintiff	§	
vs.	§	
	§	**CIVIL ACTION NO.**
THE SCOOTER STORE , LTD.,	§	
THE SCOOTER STORE - BATON ROUGE, L.L.C.,	§	**UNDER SEAL**
THE SCOOTER STORE - SAN ANTONIO, LTD.,	§	
THE SCOOTER STORE - SHREVEPORT, L.L.C. ,	§	
THE SCOOTER STORE - OKLAHOMA CITY, L.L.C,	§	
THE SCOOTER STORE - HOUSTON, LTD.,	§	
THE SCOOTER STORE - LUBBOCK, LTD.,	§	
THE SCOOTER STORE AVIATION, L.L.C.,	§	
THE SCOOTER STORE - DALLAS, LTD.,	§	
THE SCOOTER STORE - AUSTIN, LTD., and	§	
THE SCOOTER STORE, INC.,	§	
Defendants	§	

PLAINTIFF'S COMPLAINT UNDER 31 U.S.C. § 3730

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Plaintiff	§	
	§	
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	§	**CIVIL ACTION NO.**
THE SCOOTER STORE, LTD., THE SCOOTER STORE - BATON ROUGE, L.L.C., THE SCOOTER STORE - SAN ANTONIO, LTD., THE SCOOTER STORE - SHREVEPORT, L.L.C. , THE SCOOTER STORE - OKLAHOMA CITY, L.L.C, THE SCOOTER STORE - HOUSTON, LTD., THE SCOOTER STORE - LUBBOCK, LTD., THE SCOOTER STORE AVIATION, L.L.C., THE SCOOTER STORE - DALLAS, LTD., THE SCOOTER STORE - AUSTIN, LTD., and THE SCOOTER STORE, INC.,	§	**UNDER SEAL**
	§	
Defendants	§	

PLAINTIFF'S COMPLAINT UNDER 31 U.S.C. § 3730

Carol Oren (Plaintiff) submits her complaint under seal, as follows:

I.

Introduction

1. This is a *qui tam* action filed by Plaintiff pursuant to the authority granted under the False Claims Act (FCA), 31 U.S.C. §§ 3729-3733. The *qui tam* provisions of the FCA authorize a private person, acting as a "whistle blower," to bring a civil action for the person and for the government against persons who commit fraud against the government. The whistle blower, also known as a "*qui tam* Plaintiff" or "relator," is entitled to receive a percentage of any proceeds of the action or settlement of the claim as an award, subject to specified limitations and exceptions. The whistle blower is also entitled to receive an amount for reasonable expenses, plus reasonable attorneys' fees and costs, from the Defendant.

2. In her action, Plaintiff, for herself and on behalf of the United States seeks to recover damages, civil penalties, and other relief from the Defendant for false claims presented to Federal and State health insurance programs, including the Medicare and Medicaid programs. Plaintiff seeks recovery under the False Claims Act.

3. The false claims are based upon several types of unlawful conduct:

    a. fraudulent claims for medically unnecessary electric wheelchairs and power operated vehicles (POVs);

b. fraudulent claims for medically unnecessary electric wheelchair accessories;

c. fraudulent claims for medically unnecessary electric wheelchairs and POVs where Defendant violated Medicare law by providing the prescribing physician with sample "correct" CMN answers which supported medical necessity;

d. fraudulent claims for very expensive, K0011 electric wheelchairs, when inexpensive E1230 POVs are a less costly, feasible and medically reasonable alternative;

e. fraudulent claims for very expensive, K0011 electric wheelchairs, when less expensive K0010 electric wheelchairs are a less costly, feasible and medically reasonable alternative;

f. fraudulent claims for very expensive, fully-accessorized K0011 electric wheelchairs, when less expensive base K0011 electric wheelchairs without accessories are a less costly, feasible and medically reasonable alternative;

g. fraudulent claims for very expensive, K0011 electric wheelchairs, when very inexpensive K0001 standard manual wheelchairs are a less costly, feasible and medically reasonable alternative;

h. fraudulent claims for used electric wheelchairs and POVs represented to be new equipment based on "re-warranty' by the manufacturer; and

i. Fraudulent claims for used electric wheelchairs and POVs represented to be new equipment based on "re-delivery" by Defendant.

II.

The parties

4. Plaintiff, **Carol Oren,** is an individual residing in Bexar County, Texas. She brings her action against the Defendant under the Federal False Claims Act, 31 U.S.C. § 3729 *et seq.*, for violations of 31 U.S.C. § 3729, for the United States of America and for herself, pursuant to the authority granted by 31 U.S.C. § 3730.

5. Defendant, **The Scooter Store, Ltd.,** is a limited partnership with its principal place of business at 1650 Independence Drive, New Braunfels Texas 78132. Defendant's registered agent for service of process Douglas T. Harrison can be served at 1650 Independence Drive, New Braunfels Texas 78132.
6. Defendant, **The Scooter Store - Baton Rouge, L.L.C.,** is a limited liability company with its principal place of business at 1650 Independence Drive, New Braunfels Texas 78132. Defendant's registered agent for service of process CT Corporation System can be served at 1021 Main Street, Suite 1150 Houston TX 77002.
7. Defendant, **The Scooter Store - San Antonio, Ltd.,** is a limited partnership with its principal place of business at 1650 Independence Drive, New Braunfels Texas 78132. Defendant's registered agent for service of process Douglas T. Harrison can be served at 1650 Independence Drive, New Braunfels Texas 78132.
8. Defendant, **The Scooter Store - Shreveport, L.L.C.,** is a limited liability company with its principal place of business at 1650 Independence Drive, New Braunfels Texas 78132. Defendant's registered agent for service of process CT Corporation System can be served at 1021 Main Street, Suite 1150 Houston TX 77002.
9. Defendant, **The Scooter Store - Oklahoma City, L.L.C.,** is a limited liability company with its principal place of business at 1650 Independence Drive, New Braunfels Texas 78132. Defendant's registered agent for service of process CT Corporation System can be served at 350 North St. Paul St. Dallas TX 75201.
10. Defendant, **The Scooter Store - Houston, Ltd.,** is a limited partnership with its

principal place of business at 1650 Independence Drive, New Braunfels Texas 78132. Defendant's registered agent for service of process Douglas T. Harrison can be served at 1650 Independence Drive, New Braunfels Texas 78132.

11. Defendant, **The Scooter Store - Lubbock, Ltd.,** is a limited partnership with its principal place of business at 1650 Independence Drive, New Braunfels Texas 78132. Defendant's registered agent for service of process Douglas T. Harrison can be served at 1650 Independence Drive, New Braunfels Texas 78132.

12. Defendant, **The Scooter Store Aviation, L.L.C.,** is a limited liability company with its principal place of business at 1650 Independence Drive, New Braunfels Texas 78132. Defendant's registered agent for service of process Douglas T. Harrison can be served at 1650 Independence Drive, New Braunfels Texas 78132.

13. Defendant, **The Scooter Store - Dallas, Ltd.,** is a limited partnership with its principal place of business at 1650 Independence Drive, New Braunfels Texas 78132. Defendant's registered agent for service of process Douglas T. Harrison can be served at 1650 Independence Drive, New Braunfels Texas 78132.

14. Defendant, **The Scooter Store - Austin, Ltd.,** is a limited partnership with its principal place of business at 1650 Independence Drive, New Braunfels Texas 78132. Defendant's registered agent for service of process Douglas T. Harrison can be served at 1650 Independence Drive, New Braunfels Texas 78132.

15. Defendant, **The Scooter Store, Inc.** is a corporation with its principal place of business at 1650 Independence Drive, New Braunfels Texas 78132. Defendant's registered agent for service of process Douglas T. Harrison can be

served at 277 S. San Antonio St., New Braunfels Texas 78130.

III.

Filing under seal

16. In accordance with 31 U.S.C. § 3730(b)(2), her complaint is filed in camera and will remain under seal and will not be served on the Defendant until the Court so orders. A copy of the complaint and written disclosure of substantially all material evidence and information the Plaintiff possesses have been served on the United States pursuant to 31 U.S.C. § 3730(b)(2) and FED. R. CIV. P. 4(i).

IV.

Jurisdiction and venue

17. This Court has jurisdiction of this action under 28 U.S.C. §§ 1331 and 1345 and 31 U.S.C. §§ 3730 and 3732. This action arises out of violations of 31 U.S.C. § 3729 by the Defendant, and certain of the acts proscribed by 31 U.S.C. § 3729 on which this action is based occurred in this judicial district. In addition, Defendant can be found, resides, and transacts business in this judicial district, within the meaning of 31 U.S.C. § 3732(a).

18. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1395.

V.

Plaintiff's direct and independent knowledge of Defendant's fraudulent conduct, and her voluntary disclosure of the information to the government before filing her action ("original source")

19. Plaintiff gained direct and independent knowledge of the false and fraudulent claims and unlawful acts described in her complaint through her employment with Defendant. As more particularly described below, from on or about June 2002 to on or about September 2004, Plaintiff was Defendant's Medicare Part B "Director of Appeals" and Defendant's Medicare Part B "Appeals Officer." In this capacity, Plaintiff supervised the appeal of all Defendants' Medicare Part B reimbursement claims though the sequential stages of: (a) carrier Review by the Durable Medical Equipment Regional Carriers (DMERCs), (b) carrier Fair Hearings conducted by the DMERCs, (c) Administrative Law Judge (ALJ) Hearings, and (d) Medicare Appeals Council (MAC) Review. Plaintiff personally represented Defendant at thousands of Fair Hearings and ALJ Hearings. Also during the more than two years in which Plaintiff served as Defendant's Director of Appeals and Appeals Officer, Plaintiff reviewed the claims, certificates of medical necessity (CMNs) and supporting documents in virtually all of Defendant's thousands of Medicare Part B reimbursement claims that were appealed by Defendant to carrier Review, to Fair Hearing, to ALJ Hearing and to MAC Review. Also in her capacities as a Director and Officer of Defendant, Plaintiff became thoroughly familiar with virtually all aspects of Defendant's historical and current business practices relating to: providing electric

wheelchairs and POVs to Medicare Part B beneficiaries and filing reimbursement claims for that equipment with the Medicare Part B program.

20. Plaintiff personally and through her counsel voluntarily provided her knowledge of the Defendant's unlawful conduct and false and fraudulent claims to the United States before filing her action. Plaintiff first reported the false or fraudulent claims to the Federal Bureau of Investigation (FBI) on or about May or June 2004.

21. Accordingly, Plaintiff is an "original source" of the information within the meaning of 31 U.S.C. § 3730(e)(4)(A) and (B).

VI.

Preliminary statement of the Defendant's fraudulent conduct

22. Defendant is a business enterprise which exists for a single purpose and a single purpose only: to sell very expensive electric wheelchairs and POVs to Medicare Part B program beneficiaries. Year in and year out, Defendant has filed and continues to file Medicare Part B reimbursement claims for tens of thousands of a particular extremely expensive $5,000 item of durable medical equipment, the K0011 electric wheelchair, the majority of which are not medically necessary.

23. Not content with its enormous profits on the base K0011, Defendant larded as much as $1,000 in medically unnecessary "accessories" on each base K0011 electric wheelchair, transforming the equipment provided to Medicare beneficiaries into a $6,000 "Cadillac wheelchair. "

24. Plaintiff's expert review of a substantial body of Defendants reimbursement

claims, however, indicates that the majority of these electric wheelchairs and POVs are not medical necessary because the beneficiaries can ambulate with or without assistance or are otherwise mobile to a measurable extent and thus are not "bed or chair confined."

25. The fact the majority of the beneficiaries have some ability to ambulate or are otherwise mobile in their homes is demonstrated by the documentation created by Defendant's own delivery personnel at the Date of Service (DOS). This documentation, known as the In-Home Packets or IHOPs, is maintained in Defendant's files but not made available to the Medicare authorities. Plaintiff's review of an extensive sample of these IHOPs indicates that a majority of Defendant's reimbursement claims were known to be medically unnecessary at the DOS and therefore are false and fraudulent.

26. Defendant since on or about January 1994 to date has interpreted the bed or chair confinement criterion of the medical necessity coverage criteria for electric wheelchairs and POVs provided to Medicare Part B beneficiaries so as to qualify *any* beneficiary who needs *any* mobility assistance, *any* time, to perform *any* activity of daily living (ADLs) in the home. If the beneficiary needs any mobility assistance, any time with ambulation or mobility to perform any ADL, Defendant determines that the beneficiary is bed or chair confined and thus qualified medically for an electric wheelchair or POV. Acting pursuant to this interpretation, Defendant has provided electric wheelchairs and POVs to tens of thousands of Medicare beneficiaries that Defendant knew were able to ambulate or walk with or without assistance at least some of the time and in many claims

most of the time.

27. Defendant based its claims of medical necessity for electric wheelchairs and POVs provided to tens of thousands of Medicare Part B beneficiaries from at least January 1994 to date on an interpretation of medical necessity which is inconsistent with the actual language of the coverage criteria. Defendant has knowingly and willfully filed false or fraudulent claims for medically unnecessary electric wheelchairs and POVs by claiming that the electric wheelchairs and POVs were medically necessary when beneficiaries did not meet the medical necessity coverage criteria.

28. From on or about November 2002 to on or about February 2003, Defendant utilized a form called the "Physicians Supplemental Evaluation" which was sent to prescribing physicians along with the CMN. The Physicians Supplemental Evaluation form provided the prescribing physician with sample "correct" answers to the CMN medical necessity questions in violation of Medicare law. Defendant was at all times aware that suppliers are not permitted to provide prescribing physicians with "correct" answers and knowingly and willfully filed Medicare Part B reimbursement claims for electric wheelchairs and POVs that Defendant knew were not medically necessary. Defendant has knowingly and willfully filed false or fraudulent claims for medically unnecessary electric wheelchairs and POVs by claiming that the electric wheelchairs and POVs were medically necessary when beneficiaries did not meet the medical necessity coverage criteria.

29. For tens of thousands of K0011 electric wheelchairs provided to Medicare Part B

beneficiaries by Defendant since at least January 1994, the approximately $3,123-less-costly E1230 POV was "a reasonably feasible and medically appropriate alternative pattern of care which is less costly than the equipment furnished." Defendant was at all times aware that the E1230 POV was a reasonable, feasible and medically appropriate less costly alternative when Defendant knowingly and willfully filed false or fraudulent Medicare Part B reimbursement claims for K0011 electric wheelchairs.

30. For tens of thousands of very expensive K0011 electric wheelchairs provided to Medicare Part B beneficiaries by Defendant since at least January 1994, the approximately $786-less-costly K0010 electric wheelchair was "a reasonably feasible and medically appropriate alternative pattern of care which is less costly than the equipment furnished." Defendant was at all times aware that the K0010 electric wheelchair was a reasonable, feasible and medically appropriate less costly alternative when Defendant knowingly and willfully filed false or fraudulent Medicare Part B reimbursement claims for K0011 electric wheelchairs.

31. For tens of thousands of K0011 electric wheelchairs fully-equipped with convenience and comfort accessories provided to Medicare Part B beneficiaries by Defendant since at least January 1994, the approximately $850-less-costly base K0011 electric wheelchair was "a reasonably feasible and medically appropriate alternative pattern of care which is less costly than the equipment furnished." Defendant was at all times aware that the base K0011 electric wheelchair was a reasonable, feasible and medically appropriate less costly alternative when Defendant knowingly and willfully filed false or fraudulent

Medicare Part B reimbursement claims for fully-accessorized K0011 electric wheelchairs.

32. For tens of thousands of very expensive K0011 electric wheelchairs provided to Medicare Part B beneficiaries by Defendant since at least January 1994, the approximately $4,227-less-costly K0001 standard manual wheelchair was "a reasonably feasible and medically appropriate alternative pattern of care which is less costly than the equipment furnished." Defendant was at all times aware that the K0001 standard manual wheelchair was a reasonable, feasible and medically appropriate less costly alternative when Defendant knowingly and willfully filed false or fraudulent Medicare Part B reimbursement claims for K0011 electric wheelchairs.

33. From on or about January 1994 to on or about April 2004 Defendant was in the practice of picking up electric wheelchairs and POVs after the equipment had been used in the home of the beneficiary for some period of time. Defendant and/or the original equipment manufacturers "re-warranteed" used equipment Defendant reclaimed from beneficiaries. This "re-warranted" equipment was then supplied to other beneficiaries and billed as new. Defendant was at all times aware that Medicare reimbursement was approximately $1,262 less for used equipment than new equipment and knowingly and willfully filed false or fraudulent Medicare Part B reimbursement claims for new electric wheelchairs and POVs that Defendant knew were in fact used.

34. From on or about January 1994 to on or about December 2003, Defendant was in the practice of picking up used electric wheelchairs and POVs from

beneficiaries when a Medicare Part B reimbursement claim was denied for some reason other than lack of medical necessity. At some later date when the beneficiary's non-medical infirmity to Medicare Part B coverage was cured (which period might be weeks or months later), Defendant would go to the beneficiary's home, pick up the used equipment, drive around the block, re-deliver the same item of equipment and file a Medicare Part B reimbursement claim for the electric wheelchair or POV as new equipment. Defendant was at all times aware that Medicare reimbursement was approximately $1,262 less for used equipment than for new equipment and knowingly and willfully filed false or fraudulent Medicare Part B reimbursement claims for new electric wheelchairs and POVs that Defendant knew were in fact used.

35. In furtherance of its fraudulent schemes and in support of its false claims submitted to Government Health Care Programs, Defendant has knowingly and willfully created and used false records and statements.

36. By means of its fraudulent conduct, Defendant has fraudulently inflated the payments and reimbursements claimed and received from Government Health Care Programs.

37. This complaint identifies specific false claims, records and statements presented by the Defendant in furtherance of its fraudulent schemes and sets forth the basic framework, procedures, and the nature of the fraudulent schemes. Discovery will be necessary to identify each false claim, record, and statement, for the following reasons:

a. This case involves sophisticated schemes to defraud that were perpetrated by numerous individuals over all four DMERC regions and in most states;

b. The false claims, records, and statements are numerous and were presented over an extended period of time; and

c. Documents evidencing many of the false claims, records and statements are peculiarly within the possession of the Defendant.

VII.

Background

A. Plaintiff

38. On or about June 2002, Plaintiff was hired by Defendant as its Director of Appeals reporting directly to the Chief Financial Officer. She was responsible for managing and conducting the appeals of denials of Medicare Part B reimbursement claims. Defendant's denied claims have numbered in the tens of thousands and at times have totaled in value in excess of $40 million. From on or about June 2002 until on or about July 2004, Plaintiff was responsible for supervising the preparation of the claims for the Medicare Part B appeals process. This preparation consisted of assembling and reviewing documents relating to the sale and reimbursement claim, including but not limited to Center for Medicare Services (CMS) (formerly HCFA) Form 1500s, Certificates of Medical Necessity (CMNs), further development, physician case or treatment notes, medical records, correspondence with physicians, correspondence with

beneficiaries, correspondence with CMS and the DMERCs, delivery documentation (including Defendant's proprietary In-Home Packet (IHOP)) and invoicing. This documentation preparation and assembly function was performed by a staff of as many as 50 regular and temporary employees. Plaintiff was also responsible for the conduct of Fair Hearings and was Defendant's official representative at both Fair Hearings and Administrative Law Judge (ALJ) Hearings on Medicare Part B claims.

39. As part of the performance of her duties, Plaintiff has had occasion to review documentation relating to thousands of Defendant's Medicare Part B reimbursement claims, both denied and paid. She also had regular contact with the executive management of Defendant, including its then President, Doug Harrison, and regularly attended meetings reviewing of Defendant's historic business practices relating to the supply of electric wheelchairs and POVs to Medicare beneficiaries and Defendant's historic business practices relating to filing of reimbursement claims with the Medicare Part B program. On or about July 2004, Plaintiff's job duties were modified to eliminate her supervision of those employees charged with appeals file preparation and further development and her job title was changed from Director of Appeals to Appeals Officer. Plaintiff continued to be responsible for the conduct of carrier Fair Hearings and ALJ Hearings and to be Defendant's designated representative at those proceedings until her discharge on or about September 1, 2004.

B. Defendant

40. Defendant is the leading provider of electric wheelchairs and power operated vehicles (POVs) in the United States. Because the users of electric wheelchairs and POVs typically are either aged or disabled or both, most electric wheelchairs and POVs are provided to a Medicare eligible population. Because electric wheelchairs and POVs are relatively expensive items, the sales are primarily to beneficiaries eligible for reimbursement under the Medicare Part B program.

41. Defendant is a company with a highly specialized business. Virtually 100 percent of Defendant's business is providing just two products, electric wheelchairs and power operated vehicles (which are known by the acronym POVs and also colloquially as "scooters"), to a single customer, the Medicare Part B program. Although the Defendant has attempted to sell other products and occasionally will sell an electric wheelchair or POV to someone other than a Medicare Part B beneficiary, that portion of Defendant's business is insignificant.

42. Defendant operates through at least 11 separate business entities, including an array of corporations, limited liability companies and limited partnerships. On information and belief, Defendant despite the multiplicity of organizational forms operates as a single or unitary business enterprise and for simplicity and clarity Defendant is referred to in the singular throughout this complaint.

43. Defendant's business headquarters is located at 1650 Independence Drive, New Braunfels Texas 78132. Defendant operates in all four Durable Medical Equipment Carrier (DMERC) subregions, in most of the fifty states and operates more than 50 regional Distribution Centers.

C. Overview of electric wheelchair and POV reimbursement under Medicare Part B

44. Third-party payment sources, including Government Health Care Programs, insurance companies, and managed care plans (*e.g.*, health maintenance organizations) treat durable medical equipment (DME) as a separately covered and reimbursable benefit under the terms of the patient's health insurance coverage if certain conditions are met. Medicare treats DME as separately reimbursable Medicare Part B (supplementary medical benefit) benefit if medically necessary for the health of the beneficiary. Electric wheelchairs and POVs are classified as DME.

45. Payments made by the Medicare part B program for Medicare Part B (supplementary medical benefit) services that are reimbursed separately to the providers of such services are commonly referred to as "Part B payments." The beneficiaries covered by Part B payments are commonly referred to as "Part B beneficiaries."

D. Defendant derives substantial revenue from Government Health Care Programs

1. Federal and state health care programs, generally

46. Virtually all of the individual customers who are provided electric wheelchairs and POVs by Defendant are beneficiaries of federal and state health care programs. Federal health care program is defined in the Medicare fraud and abuse statute as:

> (1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government . . .; or
> (2) any State health care program, as defined in section 1320a-7(h) . . .

42 U.S.C. § 1320a-7b(f).

47. Government Health Care Programs include, but are not limited to, Medicare, Medicaid, TRICARE (which includes the Civilian Health and Medical program of the Uniformed Services, "CHAMPUS"), the Civilian Health and Medical program of the Veterans Administration ("CHAMPVA"), Federal Employees Health Benefits program ("FEHBP", *e.g.*, Mailhandlers and Government Employees Hospital Association), Railroad Retirement, and Federal workers' compensation insurance.

48. Critical to the continued viability and solvency of Government Health Care Programs are the fundamental concepts that medical providers bill the payers only for medical treatments and services that are reimbursable, legitimately medically necessary and actually performed in accordance with all applicable statutes and regulations.

49. Although there are numerous federally-funded Government Health Care Programs, the Medicare and Medicaid programs account for the majority of government spending in this area. Since 1965, the Medicare and Medicaid programs have enabled elderly, disabled, and low-income patients to obtain necessary medical services from medical providers throughout the United States.

2. Medicare

50. Medicare is a national health insurance program for people 65 years of age and

older, certain younger disabled people, and people with kidney failure. Payments from the Medicare program come from the Medicare Trust Fund, which is funded through payroll deductions and additional appropriations by the United States.

51. Medicare is divided into two parts. Medicare Part A means the hospital insurance program authorized under Part A of Title XVIII of the Social Security Act. Part A helps pay for care in hospitals and skilled nursing facilities and for home health and hospice care. Medicare Part B means the supplementary medical insurance program authorized under Part B of Title XVIII of the Social Security Act. Part B helps pay for doctor bills and for outpatient hospital care and various other medical services not covered by Part A.

52. The Medicare program is administered through the Centers for Medicare Services (CMS), an agency of the United States Department of Health and Human Services.

53. CMS contracts with fiscal intermediaries to determine and make payments for Part A and Part B benefits payable on a cost basis, and with carriers to determine and make payments for Part B benefits payable on a charge basis. There are four carriers which administer the Medicare DME benefit, known as Durable Medical Equipment Carriers (DMERCs). Each DMERC is responsible for one of four defined geographical subregions of the United States.

3. Medicaid

54. Medicaid is a public assistance program that provides payment of medical expenses for certain individuals and families with low incomes and resources.

55. The costs of the program are shared by the states and the federal government. The Federal government pays to the states its share of medical assistance expenditures, known as Federal Financial Participation ("FFP"), on a quarterly basis according to a formula described in sections 1903 and 1905(b) of the Act.

56. Each state administers its own program, establishes its own eligibility standards, determines the type, amount, duration, and scope of services that are covered, and sets the rate of payment for services, subject to broad federal guidelines.

E. Methods of payment under Government Health Care Programs

57. Several different methods of payment are used to reimburse providers and suppliers for services furnished to Government Health Care Program beneficiaries. The principal payment methods are as follows: charge basis; prospective payment; and reasonable cost basis. The applicable method is generally dependent upon provider type and service setting.

58. Generally, services must be: (i) furnished to a program beneficiary during a period of entitlement; (ii) furnished by a facility or other entity authorized by the respective government program to provide the services; and (iii) reasonable and necessary for the diagnosis or treatment of the patient. 42 C.F.R. § 410.12 (Part B); 42 C.F.R. 424.5 (Basic Conditions).

59. Reimbursement is not permitted under government programs unless adequate documentation exists in the beneficiary's medical file to demonstrate the actual performance and medical necessity of the services. If a Government Health Care Programs pays a claim and subsequently discovers that the medical

documentation is inadequate, the program is entitled to deny the claim retroactively and obtain a refund.

60. DME suppliers are generally reimbursed for medically necessary DME on a charge basis. Pursuant to this method of payment, DME suppliers are paid a fixed amount for each service according to the fee schedule adopted by a particular Government Health Care Program.

61. DME suppliers typically take assignment of the Medicare Part B beneficiary's claim for reimbursement from the Medicare Part B program. These are known as assigned reimbursement claims. The Medicare beneficiary remains liable for 20 percent of the reasonable charge or allowable for the item of DME, which 20 percent obligation is commonly referred to as the Medicare Part B "co-payment."

F. Conditions for payment of DME under Medicare Part B

62. Government Health Care Programs and many other third party payor sources treat Durable medical equipment (DME) as separately covered and reimbursable, if medical necessity requirements and certain other conditions are met.

63. DME is a benefit provided under Medicare Part B. 42 U.S.C. §1395x(n),(s)(6).

64. The Medicare benefit covers only "medically necessary" DME. 42 U.S.C. §1395y(a)(1)(A). DME is generally medically necessary under the circumstances specified by CMS in Section 280.1 Durable Medical Equipment Reference List, Medicare *National Coverage Determination Manual* (formerly Section 60-5 of the *Coverage Issues Appendix* to the *Medicare Carriers Manual*).

65. To be eligible for payment for DME under Government Health Care Programs,

the DME supplier must comply with all applicable statutes and regulations. 42 U.S.C. §1395m(a), (j).

66. The health insurance claim (HIC) form which Medicare Part B has required suppliers of services to use for many years to report and bill claims for payment, Form CMS-1500 (formerly Form HCFA-1500), contains a certification by the supplier that the services were medically indicated and necessary to the health of the patient.

67. Physicians are required to complete and execute a Certificate of Medical Necessity (CMN) to verify the medical necessity for certain items of DME. Special regulations apply to the procurement of CMNs from prescribing physicians by DME suppliers. 42 U.S.C. §1395m(j)(2).

68. The Medicare benefit also covers only "reasonable" DME. 42 U.S.C. 1395y(a)(1)(A). The reasonableness of DME is addressed by CMS in the *Medicare Carriers Manual (MCM)*. Section 2100.2 of the *MCM* provides, in pertinent part,

> . . . where there exists a reasonable feasible and medically appropriate alternative pattern of care which is less costly than the equipment furnished, the amount payable is based on the reasonable charge for the equipment . . . which meets the patient's medical needs.

G. Conditions for payment of electric wheelchairs and power operated vehicles (POVs) under Medicare Part B

69. Medical necessity specifically for POVs is addressed in part in 42 C.F.R. § 410.38(c). Medical necessity specifically for electric wheelchairs and POVs is further defined by CMS in Sections 280.1, 280.9 of the *Medicare National*

Coverage Determination Manual (formerly Sections 60-5, 60-9 of the *Coverage Issues Appendix* to the *Medicare Carriers Manual*).

70. These coverage criteria are supplemented by four virtually identical Local Medical Review Policies (LMRPs) promulgated by the DMERC regions. *See, e.g.*, LMRP *for Motorized/Power Wheelchair Bases (L11444) DMERC Region C DMEPOS Supplier Manual* (effective April 1, 2004); *LMRP for Power Operated Vehicles (L11447) DMERC Region C DMEPOS Supplier Manual* (effective April 1, 2004). The most significant criterion in the item-specific medical necessity coverage criteria for the electric wheelchair is the requirement that the Medicare beneficiary be bed or chair confined without the equipment. The most significant item-specific criterion in the medical necessity coverage criteria for the POV is the requirement that the Medicare beneficiary be "[un]able to move about their residence" without the equipment.

71. The LMRP currently effective in all four DMERC regions for electric wheelchairs provides that: "A patient who requires a power wheelchair usually is totally non-ambulatory . . ." *LMRP for Motorized/Power Wheelchair Bases (L11444) DMERC Region C DMEPOS Supplier Manual* (effective April 1, 2004). This key language of the LMRP has been the effective interpretation of the bed or chair confinement coverage criterion since 1993.

72. The LMRP currently effective in all four DMERC regions for POVs provides that: "A power operated vehicle (POV) is covered when . . . The patient's condition is such that without the use of a wheelchair [i.e., POV] the patient would not be able to move around in their residence. . ." *LMRP for Power Operated Vehicles*

(L11447) DMERC Region C DMEPOS Supplier Manual (effective April 1, 2004). This key language of the LMRP has been the effective interpretation of the total in-home use coverage criterion since 1993.

73. As set forth above, the medical necessity coverage criteria for an electric wheelchair specify that the beneficiary ". . . without the use of a wheelchair the patient would otherwise be bed or chair confined. . . " which the DMERCs have interpreted through their LMRPs to mean "usually . . . totally nonambulatory." As also set forth above, the medical necessity coverage criteria for POVs specify that ". . . without the use of the [POV] the beneficiary would not be able to move around in their residence. . ." The similarity of this language means that the coverage criteria for the two types of equipment sold by Defendant, electric wheelchairs and POVs, are intentionally slightly different formulations of the same criterion - the beneficiary must be bed or chair confined all or virtually all the time without the equipment.

74. Physicians are required to complete and execute a CMN to verify the medical necessity of electric wheelchairs as a condition of payment under Medicare Part B. *See LMRP for Motorized/Power Wheelchair Bases (L11444) DMERC Region C DMEPOS Supplier Manual* (effective April 1, 2004). Physicians are also required to complete and execute a CMN to verify the medical necessity of POVs as a condition of payment under Medicare Part B. *See LMRP for Power Operated Vehicles (L11447) DMERC Region C DMEPOS Supplier Manual* (effective April 1, 2004). CMS and its predecessor agency HCFA have promulgated a series of CMNs to be utilized in documenting medical necessity

for electric wheelchair and POV claims. The current versions of the CMNs were promulgated in 1996-97 and have been in use ever since. *See* HCFA (now CMS) Form 850 (Motorized Wheelchairs), HCFA (now CMS) Form 843 (POVs).

75. A DME supplier must represent to Medicare that it has a valid CMN on file when submitting a claim for payment for electric wheelchairs and POVs as medically necessary. The CMN itself is not submitted with the claim.

76. Medicare Part B will cover claims for electric wheelchairs only if they are the least costly medically appropriate alternative for the beneficiary. The current LMRP pertaining to electric wheelchairs provides, in pertinent part, that:

> If the documentation does not support the medical necessity of a power wheelchair but does support the medical necessity of a manual wheelchair, payment is made on the allowance of the least costly medically appropriate alternative.

LMRP for Motorized/Power Wheelchair Bases (L11444) DMERC Region C DMEPOS Supplier Manual (effective April 1, 2004).

VIII.

The Defendant's fraudulent conduct

A. False certifications and false claims for medically unnecessary electric wheelchairs and POVs

77. Virtually 100 percent of Defendant's business is providing electric wheelchairs and POVs to Medicare Part B beneficiaries. Defendant takes assignment of the beneficiaries' reimbursement claims under Medicare Part B as partial payment and files those reimbursement claims with the four regional DMERC carriers who

process those claims.

78. Beneficiaries learn of Defendant's products through a massive national advertising campaign, chiefly on television.

79. Beneficiaries place an order through Defendant's toll free telephone numbers. On information and belief, a large majority of all beneficiaries initially intend to order a POV. Based on the information provided over the telephone by the beneficiaries, Defendant's sales personnel determine which equipment to provide and which accessories to add to the base electric wheelchairs.

80. On information and belief, in excess of 85 percent of beneficiaries are actually provided a K0011 electric wheelchair, rather than the POV or scooter, the product after which The Scooter Store is named, the product which appears in Defendant's corporate logo, the product which is chiefly depicted in Defendant's advertising, and the product which most beneficiaries initially seek to order. Reimbursement for a K0011 electric wheelchair is approximately $3,123 per claim more than for an E1230 POV.

81. After the beneficiary's order is made, A CMN is forwarded to the beneficiary's physician. If the beneficiary's physician completes and returns the CMN in a way satisfactory to the Defendant, Defendant takes assignment of the beneficiary's claim, delivers the electric wheelchair or POV, and files the assigned claim for reimbursement with the DMERC. By filing a reimbursement claim with a CMS Form 1500, the Defendant certifies that the electric wheelchair or POV is medically necessary.

82. The electric wheelchair CMN (CMS/HCFA 850) utilized by Defendant does not

ask the prescribing physician whether the beneficiary is bed or chair confined without the electric wheelchair. In the absence of an actual physician certification on the key bed or chair confinement criterion, Defendant makes its own determination whether the beneficiaries are bed or chair confined whether the total coverage criteria are satisfied and whether the beneficiary qualifies medically for the electric wheelchair.

83. On information and belief, aware that the electric wheelchair CMN did not require the prescribing physician to directly address the bed or chair confinement criterion, Defendant at various times, and in various ways, attempted to redress this deficiency by obtaining documentation from the physician in addition to the CMN. All of this additional documentation took the form of forms designed and generated by Defendant. Such forms at various times included the Certification of Coverage Criteria" (CCC) form, used on or about February 2003 to date, and the "Additional Documentation Request" (ADR) form used earlier. However, Defendant's forms suffer from evidentiary deficiencies. The forms either merely requested the physician to "certify" in summary and conclusory fashion to the bed or chair confinement criterion (e.g., the CCC) or did not require the physician to directly address the bed or chair confinement criterion (e.g., the ADR).

84. Relevant beneficiary medical information relating to the key bed or chair confinement and in-home use coverage criteria for Defendant's sales to Medicare Part B beneficiaries is memorialized in documents that Defendant's sales personnel created and maintained incident to the sale. This information is reflected in two categories of documents.

85. The first category of documents memorializes the dialogue that Defendant's telephone sales personnel, known as "Mobility Consultants" or "MCs", have with beneficiaries. This dialogue, working from a prepared "script" which the Defendant maintains as closely-guarded secret, are memorialized electronically in Defendant's document know as the "e packet". On information and belief, these "e packets" are maintained in Defendant's sales files and never made available to Medicare or any third party.

86. On information and belief, the "e packet" addresses issues such as: (a) how the beneficiary at the time of order performed the ADLs; (b) whether the beneficiary at the time of order could ambulate or walk unaided; (c) whether the beneficiary at the time of order could ambulate or walk with the assistance of a cane; (d) whether the beneficiary at the time of order could ambulate or walk with the assistance of a walker; (e) whether the beneficiary at the time of order could walk with the assistance of another person; and (f) whether the beneficiary at the time of order used any type of manual wheelchair for mobility.

87. In addition, the Defendant's sales personnel or MCs also created an additional document known by various titles over time but most commonly as a "Customer Verification of Medical Necessity" or "CVMN." The CVMN maintained by Defendant memorializes some of the same types of information.

88. On information and belief, this "e packet" and "CVM" sales documentation in a majority of the claims indicates that the electric wheelchair beneficiary was not bed or chair confined and that POV beneficiary did not require the POV for in-home mobility. On information and belief, this "e packet" and "CVM" sales

documentation indicates in a majority of the claims that the beneficiary at the time of order could and did either: (a) ambulate or walk unaided, (b) ambulate or walk with the assistance of a cane, (c) ambulate or walk with the assistance of a walker, (d) ambulate or walk with the assistance of another person, or (e) move about with the assistance of some type of manual wheelchair. On information and belief, the "e packet" and "CVM" sales documentation will indicate in only a minority of the claims that the beneficiary had no ability to ambulate or walk at all or was totally immobile within the home at the time of order.

89. Information relating to the key bed or chair confinement coverage criterion for Defendant's sales of electric wheelchairs and the in-home use criterion for POVs is also contained in a second category of documents that Defendant's delivery personnel created and maintained incident to delivering the equipment to beneficiaries' homes. This delivery documentation includes, but is not limited to the "The Scooter Store™ In-Home Patient Evaluation" and the "The Scooter Store™ Home Evaluation." This delivery documentation is referred to by Defendant collectively as the In-Home Packet or IHOP. Samples of these IHOPS, with the beneficiary identities redacted, are attached hereto as Exhibit A.

90. Plaintiff has reviewed hundreds of these IHOPs. Her review indicates that in a majority of the claims the electric wheelchair beneficiary was not bed or chair confined and the POV beneficiary did not require the POV for in-home mobility. The IHOPs reviewed indicate that in a majority of the claims that the beneficiary at the time of delivery (the Medicare Date of Service or DOS) could and did either: (a) ambulate or walk unaided; (b) ambulate or walk with the assistance of

a cane; (c) ambulate or walk with the assistance of a walker; (d) ambulate or walk with the assistance of another person; or (e) or move about with the assistance of a manual wheelchair. The IHOPS reviewed indicate in only a minority of the claims that the beneficiary had no ability to ambulate or walk or was totally immobile within the home at the time of delivery (DOS).

91. On information and belief, Defendant interprets the bed or chair confinement criterion of medical necessity for electric wheelchairs provided to Medicare Part B beneficiaries to include *any* beneficiary who needs *any* mobility assistance, *any* time, to perform *any* activity of daily living (ADLs). On information and belief, if the beneficiary needs any mobility assistance, any time with ambulation or to perform any ADL, Defendant determines that the beneficiary is bed or chair confined and thus qualified medically for an electric wheelchair.

92. The actual coverage criteria for electric wheelchairs, however, require actual bed or chair confinement. The LMRP for electric wheelchairs cited above clarifies bed or chair confinement by providing that beneficiaries are bed or chair confined if they are "usually . . . totally nonambulatory." Giving these words their plain meaning, a beneficiary who is *normally* completely non-ambulatory or immobile without assistance could on *rare* occasions be ambulatory and still qualify as bed or chair confined.

93. On information and belief, Defendant interprets the complete in-home use criterion of medical necessity for POVs provided to Medicare Part B beneficiaries to include *any* beneficiary who needs *any* mobility assistance, *any* time, to perform *any* activity of daily living (ADLs) in the home. On information and belief,

if the beneficiary needs any in-home mobility assistance, any time with ambulation or to perform any ADL, Defendant determines that the beneficiary's in-home use is complete thus qualified medically for a POV.

94. The actual coverage criteria for POVs, however, require that the in-home use to be *total*. The LMRP for POVs cited above clarifies in-home use by providing that "A power operated vehicle (POV) is covered when . . . The patient's condition is such that without the use of a wheelchair [i.e. POV] the patient would not be able to move around in their residence. . ." Giving these words their plain meaning, a beneficiary can qualify for a POV only if they are *completely* unable to move about their residence or home without the POV.

95. Acting pursuant to Defendant's unique interpretations, Defendant has provided electric wheelchairs and POVs to tens of thousands of Medicare beneficiaries that Defendant knew were able to ambulate or walk with or without assistance of a cane walker or use a manual wheelchair within the home at least some of the time and in many claims most or all of the time.

96. Defendant based its claim of medical necessity for electric wheelchairs and POVs provided to tens of thousands of Medicare Part B beneficiaries from at least January 1994 to date on an interpretation of medical necessity which is inconsistent with the actual language of the coverage criteria.

97. Plaintiff's review of an extensive sample of thousands of Defendant's claim files and hundreds of Defendant's claim files specifically containing In- Home Packets (IHOPs) has indicated the following:

a. that notes made by Defendant's own delivery employees and included in the IHOPs completed incident to delivery in a very high percentage of claims indicate that Defendant's employees observed the beneficiary move about without assistance or with the assistance of a cane, walker or another person, or by using a manual wheelchair at the time of delivery (the DOS);

b. that in the majority of the claims with an IHOP, there is evidence the beneficiary used the electric wheelchair or POV chiefly or exclusively outside the home and was able to ambulate within the home without the electric wheelchair or POV at the DOS;

c. that in the majority of the claims with an IHOP, there is evidence that even those beneficiaries who did use the electric wheelchair or POV within the home were otherwise able to move about for significant distances within the home with the assistance of a cane, walker or another person, or by using a manual wheelchair at the DOS;

d. that in the majority of the claims with an IHOP, there is evidence that those beneficiaries who received POVs rarely used them within the home (a key criterion in the coverage criteria specifically for POVs is that they be used *in the home*), relying instead on ambulation or assisted ambulation, or a manual wheelchair for in-home mobility at the DOS;

e. that of thousands of prescribing physicians' case or treatment notes obtained in further development and reviewed by Plaintiff, no more than a handful actually referenced the need for an electric wheelchair or POV; and

f. that the thousands of prescribing physicians' case or treatment notes obtained in further development and reviewed by Plaintiff rarely disclosed a beneficiary condition which equated to bed or chair confinement.

98. On information and belief, for the period when Defendant utilized the IHOP form and procedure, on or about September 2002 to on or about March 2004, there exists clear documentation in a majority of claims that the bed chair confinement criterion and in-home criterion are not satisfied because the beneficiary was not bed or chair confined and was to some extent mobile within the home when

receiving the electric wheelchair or POV on the DOS. On information and belief, the evidence of lack of medical necessity inadvertently created by Defendant's delivery personnel in the IHOP process accurately mirrors the lack of medical necessity for Defendant's claims over the entire period from at least January 1994 to date.

99. On information and belief, for the period when Defendant utilized the IHOP form and procedure, on or about September 2002 to on or about March 2004, there exists clear documentation in a majority of claims that the in-home use criterion for POVs is not satisfied because the beneficiaries obtained and used the POV for primarily or exclusively for trips outside the home.

100. On information and belief, Defendant ceased utilizing the IHOP on or about March 2004 because it determined it should not continue to create an actual written record which tended to show that the equipment being delivered was not medically necessary.

101. Defendant from at least January 1994 to date has submitted to Medicare and other Government Health Care Programs tens of thousands of false and fraudulent claims for payment of medically unnecessary electric wheelchairs and POVs. Most of the beneficiaries for which Defendant has submitted and continues to submit claims for electric wheelchairs and POVs did not and do not meet the coverage criteria for electric wheelchairs and POVs as a matter of medical necessity.

102. On information and belief, based on Plaintiff's extensive review and analysis of Defendant's claims documentation and internal records, as many as 75

percent of Defendant's Medicare Part B reimbursement claims for electric wheelchairs and POVs since at least January 1994 to date were and are not medically necessary.

103. Tens of thousands of Defendant's reimbursement claims for K0011 electric wheelchairs as indicated in the table below (reflecting the Third Quarter 2004 DMERC Region D, California allowables) were paid from January 1994 to date by Government Health Care Programs in the amount of approximately $5,046 per claim. Thousands of Defendant's false and fraudulent claims for E1230 POVs as indicated in the table below were paid from at least January 1994 to date by Government Health Care Programs in the amount of approximately $1,923 per claim.

	K0011	K0010	E1230	K0001
New	$5,046.00	$4,259.90	$1,922.52	$54.62/month
Used	$3,784.00	$3,194.93	$1,520.49	

104. Tens of thousands of Defendant's reimbursement claims for K0011 electric wheelchairs and POVs were over paid from at least January 1994 to date by Government Health Care Programs in the amount of approximately $5,046 to $1,923 per claim.

105. Defendant was at all times aware of the actual coverage criteria and knowingly and willfully filed false Medicare Part B reimbursement claims for electric wheelchairs and POVs provided to beneficiaries that Defendant knew were not medically necessary.

106. From at least January 1994 to date, all of Defendant's reimbursement claims

for electric wheelchairs and POVs have been routinely certified by Defendant as medically necessary, regardless of the beneficiary's condition and regardless of the truth or falsity of that representation. Most of the beneficiaries did not meet the criteria for electric wheelchairs and POVs as a matter of medical necessity, and the certifications of medical necessity as to those beneficiaries were, therefore, false. The false certifications of medical necessity were intended to support, and were used to support, false claims for reimbursement submitted by Defendant to Medicare, Medicaid, and other Government Health Care Programs.

107. Defendant, with knowledge of the false certifications, has routinely presented false and fraudulent claims for payment of medically unnecessary electric wheelchairs and POV to Medicare, Medicaid, and other Government Health Care Programs.

108. A sample list, with the beneficiary identities redacted, of false and fraudulent claims in which Defendant was paid for electric wheelchairs and POVs which were not medically necessary because the beneficiaries were otherwise mobile all or part of the time within the home with the assistance of a cane, walker, or another person or manual wheelchair on the DOS is attached hereto as Exhibit B.

B. False certifications and false claims for medically unnecessary comfort and convenience accessories for electric wheelchairs

109. From at least January 1994 to date, Defendant added "accessories" to almost every electric wheelchair that it provided to Medicare Part B beneficiaries.